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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,739	09/18/2001	Pierre Michetti	06132/011002	9451

21559 7590 11/20/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/20/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,739

Applicant(s)

MICHETTI ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed August 29, 2003 is acknowledged and has been entered. Claim 1 has been amended. Claims 1-19 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or the comments with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The terminal disclaimer filed on August 29, 2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6290962 has been reviewed and is accepted. The terminal disclaimer has been recorded.
4. The terminal disclaimer filed on August 29, 2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 5837240 has been reviewed and is accepted. The terminal disclaimer has been recorded.
5. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in

the recitation of “substantially purified”; what are the metes and bounds of substantially purified? Where is support for the recitation of “substantially” in the specification? Claim 10 is vague and indefinite in the recitation of a “*H. felis* disease”; exactly what is a *H. felis* disease? What does Applicant intend?

6. Claims 1-3, 5, 8-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al (Infection and Immunity, 1990, 58/4:992-998) taken with Czinn et al (5538729).

Hu et al teaches the isolation and purification of urease from *H. pylori* (abstract; methods and materials; p. 994). Hu et al teaches that *H. pylori* causes peptic ulcer disease and is associated with chronic active gastritis, the development of gastric ulcer and non-ulcer dyspepsia (p. 992, col. 1). Hu et al teaches that *H. pylori* produces what appears to be a highly active urease and that urease may act as a virulence factor for *H. pylori* and contribute to gastric mucosal damage (p. 992). Hu et al teaches that urease of *H. pylori* is a major protein of this species, present as greater than 5% of the soluble protein (p. 996). Hu et al teaches the ureB subunit of urease as well (p. 997). Hu et al also teaches that there is a strong serum IgG response directed towards the urease protein (p. 992). The prior art teaches the method of administering the urease to an animal (methods and materials). The prior art teaches the claimed invention except for the specific method of treating gastrointestinal disease in a mammal.

However, Czinn et al teaches a method of treating gastroduodenal diseases (gastritis, ulcers, gastric cancer, duodenal ulcer diseases) comprising administering a *Helicobacter* antigen (abstract; col. 1; claims). Czinn et al teaches oral administration as well as a mucosal adjuvant, cholera toxin/B subunit (col. 2; col.

4). The patent teaches a suitable dosage of 10 micrograms to 10 milligrams (col. 4). Since Hu et al suggests that the urease is one of the very prominent soluble proteins in *H. pylori*, that *H. pylori* is responsible for certain gastrointestinal diseases and that urease may act as a virulence factor as well as the fact that it generates a strong IgG response it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a purified protein, urease, from *H. pylori*, in the methods taught by Czinn et al for the treatment of gastrointestinal diseases with a reasonable expectation of success. Czinn et al teaches treating a mammal using a whole lysate, however the method would have yielded better results and been obvious to a person of ordinary skill in the art at the time the invention was made to administer a purified *H. pylori* urease protein, rather than a whole lysate to a mammal in the treatment of gastroduodenal diseases. Czinn et al also suggests the use of a *H. pylori* antigen (see abstract; summary of the invention). The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

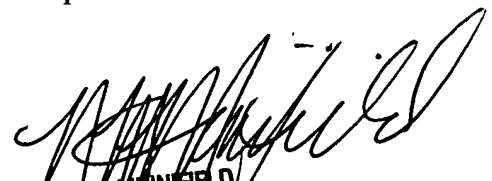
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


NTA MINNIFIELD
PRIMARY EXAMINER
1645
11/16/03